

### **REMARKS**

This responds to the Final Office Action mailed on November 26, 2008.

No claims are amended or cancelled. Claims 1-19 are now pending in this application.

#### **§103 Rejection of the Claims**

Claims 1-5, 7, 8 and 16-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

#### **Claims 1-5 and 7-8**

Applicant traverses the rejection of claim 1. Applicant believes claim 1 is not obvious in view of the cited references since, even if combined, each limitation recited in the claim is not found in the cited combination. For instance, Applicant cannot find in the combination: a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

The Office Action states that Dutcher includes “a non-soluble coating containing a drug on a portion of the exterior surface of the lead (e.g. col. 2, lines 45-65, figure 5, 138, or 138 and 133)”. (Page 3 of Office Action). Applicant traverses this characterization of the Dutcher reference. That portion of the Dutcher reference discusses a sheath 133 on a wire 131 and a drug plug 138. The drug plug 138 is a plug of material filling the interior of wire 131. However, even if members 133 and 138 are combined they do not include: the insulating material including an active ingredient, as recited in claim 1. Sheath 133 does not include any active ingredient and drug plug 138 is not an insulating material that conforms to the outer surface of the helix. As described in the Dutcher reference: “The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 is positioned in contacting relationship with the heart tissue.” (Col. 4, lines 53-56). Accordingly, the drug of drug plug 138 and sheath 133 are not part of a structure that includes a non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

The Response to Arguments section states that “Dutcher shows in figures 5, 8, and 9, the plastic drug plug, 138/238, covering/coating a portion of the outer surface of the helix.” (Page 9 of Office Action. However, drug plug 138/238 does not cover or coat the outer surface of the helix so as to conform to the outer surface of the helix, as recited in claim 1.

The Response to Arguments further states that “Dutcher includes insulative coating, 133 or 233 (e.g. col. 3, line 57), that conforms to an outer surface of the helix and contains an active ingredient from drug plug, 138, due to the migration of the drug from the plug or touching of the plug to insulative coating, 133 or 233.” (Page 10 of Office Action). However, claim 1 recites: the insulating material including an active ingredient. It does not recite that the drug is adjacent the insulating material. Also, as discussed above, the Dutcher reference describes that: “The drug will be dispensed from the outer surface of plug 138 to the heart tissue as plug 138 is positioned in contacting relationship with the heart tissue.” (Col. 4, lines 53-56). Thus, the Dutcher reference itself does not state that the drug is included or contained in the insulative coating 133.

Claims 2-5, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

#### Claims 16-19

Applicant traverses the rejection of claim 16. Applicant believes claim 16 is not obvious over the cited references since each limitation recited in the claim is not found in the cited combination. For instance, Applicant cannot find in the combination, a fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 16. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 1-5, 7, 8 and 16-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bisping (U.S. Patent No. 4,886,074) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Applicant traverses the rejection of claim 1. Applicant believes claim 1 is not obvious in view of the cited references since there is no reason or suggestion to combine the references.

Here, Altman discusses different coatings for an implantable device which is for “effective elimination of an arrhythmogenic site.” (Abstract). In contrast, Bisping relates to an implantable electrode type lead assembly. (Abstract). Thus, there appears to be no motivation or reason to apply any of Altman’s or Hoffman’s discussions to the lead of Bisping, since they are used for generally different purposes.

In the Response to Arguments section, the Office Action states that “both Altman and Bisping are in the same field of endeavor, i.e. fixation helixes used to screw into the heart.” (Page 10 of Final Office Action). However Bisping gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 – col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrhythmogenic sites. Merely because Altman discusses a helix shape for the arrhythmogenic treatment device does not mean that his disclosure applies to a helix used for a completely different purpose, such as the Bisping helix, which is used as a fixation device to hold an electrode in place.

Regarding the Hoffman reference, the Hoffman reference discusses a lead having a hydrogel coating. (Abstract). It discusses nothing of an insulative coating for a helix. The Hoffman reference teaches away from such an application of the hydrogel coating. For instance, at col. 6, lines 7-12, Hoffman states that “It is not necessary to apply the hydrogel to the connectors, the pacing tip electrode, or the region of the lead that will be coiled into the subcutaneous area. If the pacing tip electrode were coated, tissue would not grow into the pores, thereby not providing firm stabilization of the lead at the tip.”

Claims 2-5, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 16-19

Applicant traverses the rejection of claim 16. Applicant believes claim 16 is not obvious over the cited references since there is no reason or suggestion to combine the references. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 1, 2, 3, 7, 8 and 16-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Dutcher et al. (U.S. Patent No. 5,217,028).

Applicant traverses the rejection of claim 1. Applicant believes claim 1 is not obvious over the cited references since each limitation recited in the claim is not found in the cited combination. For instance, Applicant cannot find in the combination: a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

As discussed above, the Dutcher reference discusses a sheath 133 on a wire 131 and a drug plug 138. However, even if combined, this does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, "the insulating material including an active ingredient." The discussion above regarding the Dutcher reference is incorporated herein by reference.

Claims 2-3, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 16-19

Applicant believes claim 16 is not obvious over the cited reference since each limitation recited in the claim is not found in the cited reference. For instance, Applicant cannot find in the combination: a fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 16. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 1,2, 3, 7, 8 and 16-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Grassi (U.S. Patent No. 4,624,265) in view of Rockland et al. (U.S. Patent No. 4,010,758) and Altman (U.S. Patent No. 5,551,427) or Hoffman (U.S. Patent No. 5,902,329).

Applicant traverses the rejection of claim 1. Applicant believes claim 1 is not obvious in view of the cited references since there is no reason or suggestion to combine the references.

Here, Altman discusses different coatings for an implantable device which is for “effective elimination of an arrhythmogenic site.” (Abstract). In contrast, Grassi relates to an implantable electrode for a pacemaker. (Abstract). Thus, there appears to be no motivation or reason to apply any of Altman’s discussion to the lead of Grassi, since they are used for generally different purposes. The Grassi disclosure gives no indication of a need for any of the Objects of Invention described in Altman at col. 6, line 20 – col. 7 line 3, where the Altman disclosure discusses different purposes of the device to treat arrhythmogenic sites. Merely because Altman discusses a helix shape for the arrhythmogenic treatment device does not mean that the disclosure applies to a helix used for a completely different purpose, such as the Grassi helix, which is used as a fixation device to hold an electrode in place.

Regarding the Hoffman reference, the Hoffman reference discusses a lead having a hydrogel coating. (Abstract). It discusses nothing of an insulative coating for a helix. The Hoffman reference teaches away from such an application of the hydrogel coating. For instance, at col. 6, lines 7-12, Hoffman states that “It is not necessary to apply the hydrogel to the connectors, the pacing tip electrode, or the region of the lead that will be coiled into the subcutaneous area. If the pacing tip electrode were coated, tissue would not grow into the pores, thereby not providing firm stabilization of the lead at the tip.”

Claims 2-5, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 16-19

Applicant traverses the rejection of claim 16. Applicant believes claim 16 is not obvious over the cited references since there is no reason or suggestion to combine the references. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

Claims 4 and 5 were rejected under 35 U.S.C. §103(a) as being unpatentable over either modified Grassi (U.S. Patent No. 4,624,265) rejected above in view of Bisping (U.S. Patent No. 4,886,074), Jammet (U.S. Patent No. 5,447,534), or Ocel et al. (U.S. Patent No. 5,837,006).

Claims 4 and 5 depend from claim 1 and are not obvious over the cited references for the reasons discussed about regarding claim 1.

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over either modified Bisping (U.S. Patent No. 4,886,074) or either modified Grassi et al. (U.S. Patent No. 4,624,265) as applied to claim 1 above and further in view of Ocel et al. (U.S. Patent No. 5,837,006) or Vachon (U.S. Patent No. 5,531,780).

Claim 6 depends from claim 1 and is not obvious over the cited references for the reasons discussed about regarding claim 1.

**CONCLUSION**

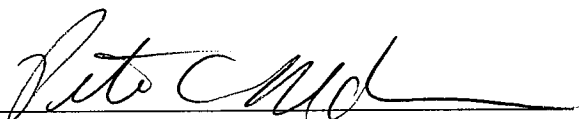
Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 359-3267 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

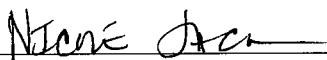
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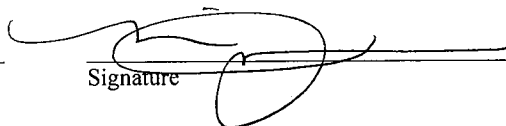
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Date 1/26/09

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 26, 2009.

  
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